Vaccine Identification Standards Initiative (VISI)

Minutes of Conference Call
2000 July 26
11:00 am - 1:00 pm EDT

CALL PARTICIPANTS

Bruce Weniger (moderator)	National Immunization Program/CDC
Bindi Patel	National Immunization Program/CDC
Aparna Rao	National Immunization Program/CDC/DMD
Bill Purvis	Center for Biologics Evaluation and Research/FDA
Karen Chaitkin	Center for Biologics Evaluation and Research/FDA
Fred Varrichio	Center for Biologics Evaluation and Research/FDA
Jane Gilbert	Chiron Corporation
Wikke Wallop	Health Canada
Ron Filipski	Aventis Pasteur
Jim Mundt	Merck Vaccine Division
John Roberts	Uniform Code Council
Joanne Kim	American Academy of Pediatrics
Jose Padilla	Texas Department of Health
Elma Garcia	Texas Department of Health

SUMMARY

Introductions

Dr. Bruce Weniger welcomed all VISI participants, who identified themselves and their institutions in turn.

Printing Technology Subcommittee Meeting

Dr. Weniger reminded VISI members about the barcode printing technology subcommittee meeting to be held on Thursday, 27 July 2000 in Lawrenceville, NJ, at the UCC headquarters. This meeting will address the challenge of high-speed online printing of Reduced Space

Symbology (RSS)/Composite barcodes, as VISI will specify on peel-off stickers for vaccine vials and syringes. A respected expert in printing bar codes on manufacturer production lines, Rick Fox, will present his findings and advice about high-speed online printing. Any manufacturers which require label printing rates higher than 300 per minute for their production lines should contact UCC, as this rate is the challenge that Mr. Fox is being asked to address.

VISI Presentations

Dr. Weniger updated VISI members about recent VISI presentations made to both the National Vaccine Advisory Committee (NVAC) in Washington on 22-May-2000 and the Advisory Committee on Immunization Practices (ACIP) in Atlanta on 22-June-2000. Both presentations generated great interest and anticipation for VISI.

Ms. Bindi Patel also announced she will be presenting about VISI at the "Promoting and Standardizing Bar Coding on Medication Packaging: Reducing Error and Improving Patient Care" meeting to be held in Chicago on 7-August-2000.

Discussion of specific VISI components

1. Peel-off vaccine vial/syringe sticker prototypes and barcoding

- Dr. Weniger asked whether the newly posted RSS and UCC-EAN 128 barcodes on the VISI website were in conformance with UCC standards. Mr. John Roberts stated that the draft prototypes were in conformance and the characters and human readables were fine.

- Frank Sharkey, however, scanned all the "2000-Jun-15" and "2000-Jun-16" .pdf file vaccine barcode prototypes on the VISI website and reported a few problems, as follows:
    1. **Td** vaccine (file RSS-Wal-Td.pdf): RSS Limited at 4 dots fails to scan
    2. **HIB** vaccine (file RSS-PMC-API-HIB.pdf): OK
    3. **PNU_{ps}** vaccine (file RSS-MRK-PNUps.pdf): OK
    4. **DTP_a-HIB** (file RSS-PMC-DTPa-HIB.pdf): RSS Limited at 4 dots contains duplicate entries of the NDC (SCC-14) but no expiration or lot numbers.
    5. **DTP_a-HIB** (file RSS-PMC-DTPa-HIB.pdf): Sample C. of barcoding on cartons contained an erroneous expiration date embedded in the barcode ("991130", carried over from the **Td** sample) instead of the intended human readable "990222".

- Dr. Weniger encouraged VISI participants to look over the updated sample sticker prototypes illustrating multiple peel-off stickers. Last month, there was discussion regarding the entire label peeling off versus having a perforation with part of the label staying fixed to the vial. If so, then the RSS barcode and accompanying human-readable information might need to be printed in duplicate, so they remain on the vial, as well. The current prototypes on the website do not yet illustrate this feature.

2. National Drug Code (NDC) Database

- Ms. Bindi Patel updated the group about recent changes and additions to the NDC database. She informed the group that several new fields have been added to the NDC database form, including "Product Insert Web Address" and "FDA Approval Date". She further added that the latest influenza vaccines, including the 1999-2000 formulas, have been entered into the database. She encouraged vaccine manufacturers to review their products listed in the database and send her any additions or revisions, if necessary.

- Dr. Weniger brought up the issue of mentioning in the NDC database under the "manufacturer(s)/distributor(s)" field the prior names of manufacturers/distributors to reflect corporate renamings, even though the NDC remains the same. This would apply to Pasteur Merieux Connaught becoming Aventis Pasteur. VISI participants agreed that using the term "formerly" in the parenthesis was better than "includes" to indicate a corporate name change.

- Dr. Weniger also asked the group whether the database should provide greater detail in distinguishing between the actual manufacturers of the vacine and their U.S. distributors. Some VISI members indicated this might become too complex. Mr. Bill Purvis added that the FDA only requires the manufacturer and distributor information. When in doubt, the listing should give precedence to the U.S. distributor responsible for sales, technical questions from the public, and surveillance of adverse events resulting from the product, rather than its actual manufacturer, if different.

3. Discussion of *Vaccine Facts* information sidebars prototypes

- Dr. Weniger shared some feedback from Dr. John Grabenstein's, the editor of *ImmunoFacts*®, and his suggestions about several other VISI components. These were discussed, as follows.

- Some VISI participants indicated that the "trace components" field was very broad. It was suggested to use "See Package Insert" instead of listing the varying types of trace components, although this might negate the purpose of the trace components field.

- Another suggestion from Dr. Grabenstein for trace components when quantities are mentioned and the packaging is multi-dose is to specify whether quantities are "per dose" or "per container". VISI members agreed that this should be done.

- VISI members also agreed that the "Volume" field is ambiguous, since it could be interpreted as dosage volume or container volume. It was agreed upon that this field name might be changed to "Contents" to reflect container volume, and dose volumes be otherwise dealt with.

- Some prototype vaccine sidebar panels listed a telephone contact number for the manufacturer or distributor, while others did not have this information (reflecting the content of actual vaccine cartons from which they were derived). Many VISI members agreed that having a toll-free telephone contact number was an excellent idea. Mr. Purvis stated that VISI should encourage toll-free telephone numbers on all vaccine packaging. But he warned that these numbers should not link the caller directly to the sales or marketing departments, but rather to the medical information department. Dr. Weniger asked whether it would be OK with FDA for a toll-free number to link to a single "triaging" call center, which could refer the inquiry to medical information, sales, marketing, or whatever unit was relevant to the caller's inquiry. Mr. Purvis indicated it would be OK.

4. Discussion of standardized vaccine abbreviations

- Ms. Wikke Wallop felt that the standardized vaccine abbreviations were very confusing. Dr. Weniger stated that standardized abbreviations for vaccines and manufacturers might be advantageous on very small peel-off stickers when space limitations prevent spelling out the full generic names of very large combination vaccines, and the full names of manufacturers or distributors.

- There was a discussion of "**RUB**" (rubella) being confused with "rubeola" in Spanish. However, Mr. Jose Padilla stated that measles disease is "sarampión" in Spanish, and he did not foresee this as a problem. Dr. Weniger stated that he will verify these terms in dictionaries. [Followup: "Rubeola" is an ancient term that has been used for both measles (morbilli) and german measles (rubella, *rubeola notha* [spurious]). Thus, the ambiguous term rubeola should be avoided entirely and ignored.]

- VISI members discussed other recommendations and questions raised by Dr. Grabenstein which included:

  - Consistent with VISI's naming principles, change the draft abbreviation for smallpox vaccine from "**SPX**" to "**SMA**", Klebsiella vaccine from "**KLB**" to "**KLE**", and glanders vaccine from "**GLD**" to "**GLA**". Agreed.
  - Avoiding "LPS" as a main root abbreviation so it won't be misinterpreted as the lipopolysaccharide specifier "$_{\mathbf{LPS}}$". Agreed.
  - Would "$_{\mathbf{pa}}$" be suitable as a specifier for a vaccine consisting solely of recombinant "protective antigens"? [Answer: yes, at user's discretion.]
  - Replacing the "antitoxin" specifier "$_{\mathbf{ant}}$" with "$_{\mathbf{atx}}$". Agreed.
  - Eliminating the "$_{\mathbf{tox}}$" subscript from *Clostridium botulinum* vaccine ("**CLB**$_{\mathbf{tox}}$") as redundant for this toxoid vaccine. Agreed. [Subsequently, this vaccine's main root abbreviation renamed "**BOT**"]
  - Specifying *Clostridium botulinum* vaccines by their serogroups (A, B, C, etc.).

Agreed.

- Consider listing combination vaccine components alphabetically. Agreed that a convention should be developed for ordering the listing of components in abbreviations of combination vaccines. [This has been done in August drafts].
- Is "**HBIG**" grandfathered? If not, recommend "**HBV$_{ig}$**". Agreed.
- Change "**IG**" specifiers to be "$_{im}$" and "$_{iv}$". Agreed.
- Specifying types "$_{A}$" or "$_{B}$" for INF vaccines. This is already an option of abbreviation users, when desired for specificity.
- Concern that Lyme disease vaccine (**LYM**) will be confused with some monoclonal antibodies targeting lymphomas. Unresolved.

5. Discussion of standardized manufacturer abbreviations

♦ Dr. Grabenstein's comments on the standardized manufacturer abbreviations were discussed:

- Changing 2-letter abbreviations to 3-letter abbreviations (e.g., BPC instead of BP). [Followup: Up to four characters are now available for manufacturer abbreviations; Aviron has requested a change from "AVI" to "AVIR". BioPort Corporation will be queried for its abbreviation preference.]
- Rethink Centeon abbreviation ("CEN") so it won't be confused with Centocor's. Agreed. [Centeon changed to CTN", Centocor abbreviated "CTC".]
- Changing Medeva plc abbreviation ("MDV") to avoid misinterpretation for "multidose vial". Not agreed.
- Adding additional major antibody manufacturers (e.g., American Red Cross, etc.) to the abbreviation list. Agreed. [Done in August drafts.]
- Avoiding any "MED" abbreviation to avoid confusing Medeva and Medimmune. Agreed. [Followup: Medimmune changed to "MDI", Medeva retained "MDV".]

Next Steps

♦ Another conference call was set for Wednesday, September 13, at 11:00am. The following call information will be repeated and distributed via email closer to the event:

Call name:	VISI
Date:	Wednesday, 13 September
Time:	11:00 - 1:00 am EDT (8:00-10:00 am PDT)
Phone no.:	[+1] 404-639-3277
Toll-free in US:	1-800-311-3437
Access Code:	###### [Deleted from website-posted document. Contact Bindi for access no.]

VISI Contact

Bindi I. Patel
Vaccine Development Fellow
VSDB/ National Immunization Program / CDC (MS E-61)
1600 Clifton Road
Atlanta, GA 30333
Tel: (404) 639-1861
Fax: (404) 639-8834
E-mail: bpatel@cdc.gov or visi@cdc.gov